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ATTORNEYS FOR PLAINTIFF
UNITED STATES OF AMERICA

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MONTANA

BUTTE DIVISION

UNITED STATES OF AMERICA, **Plaintiff,** **vs.** **CANADADRUGS.COM LTD. PARTNERSHIP, ROCKLEY VENTURES LTD., and RIVER EAST SUPPLIES LTD.,** **Defendants.**	**14-CR-27-BU-DLC** **UNITED STATES' SENTENCING MEMORANDUM**

The Defendants Canadadrugs.com Ltd. Partnership, Rockley Ventures Ltd., and River East Supplies Ltd. (hereinafter, "Defendants"), operated a large-scale

unapproved and misbranded prescription drug smuggling and distribution scheme that included operations in Canada, the United Kingdom, Barbados, and the United States. The Defendants knowingly imported into the United States substantial quantities of a range of prescription drugs, including clinical cancer medications, that were meant for foreign markets, were not approved by the United States Food & Drug Administration as required by law for sale in the United States, and were misbranded under the Food Drug and Cosmetic Act. The Defendants conducted the scheme with the intent to defraud and mislead various United States federal regulatory and law enforcement authorities, including the FDA, as well as consumers in the United States. Additionally, the illegal smuggling and distribution scheme resulted in the Defendants distributing counterfeit versions of the cancer drugs Avastin and Altuzan in the United States. Subsequently, the Defendants failed to notify United States or foreign regulatory or law enforcement authorities upon learning that the drugs were suspect. Testing conducted by FDA's Forensic Chemistry Center confirmed that the counterfeit Avastin and Altuzan did not contain bevacizumab, the active ingredient that is found in legitimate versions of the product.

A plea hearing and sentencing hearing are scheduled in this case for April 13, 2018 (along with the plea and sentencing hearings of the related individual co-

defendant, Canada Drugs CEO Kristjan Thorkelson). The United States and the Defendants jointly request that the Court accept the Defendants' plea and plea agreement, which is governed by Rule 11(c)(1)(C), *Federal Rules of Criminal Procedure*, and impose a sentence on the organizational defendants of 5 years probation, a fine of $5 million, a forfeiture of $29 million, special assessments of $400 and $125, respectively, for the felony and misdemeanor charges, and additional conditions of probation as detailed further below, which include causing the permanent cessation of the sale of all unapproved, misbranded, adulterated, or counterfeit drugs in the United States, and cooperating fully with the United States in ongoing related and future criminal prescription drug investigations.

THE CHARGES

In a Superseding Information filed in this case on December 12, 2017, all three corporate Defendants were charged in Count I with committing, between in or about January 2009 through 2012, the felony crime of introducing, and delivering for introduction, into interstate commerce misbranded prescription drugs, with intent to defraud and mislead, contrary to 21 U.S.C. §§ 352(c), 352(o), and 352(f)(1), in violation of 21 U.S.C. §§ 331(a), and 333(a)(2) and aiding and abetting, in violation of 18 U.S.C. § 2. In that same Superseding Information, in Count II, corporate Defendants Rockley Ventures Ltd. and River East Supplies

Ltd. were charged with committing, between November 2011 and January 2012, the misdemeanor crime of selling, and causing to be sold, counterfeit prescription drugs, namely counterfeit Avastin, in violation of 21 U.S.C. §§ 331(i)(3), 333(a)(1), and aiding and abetting, in violation of 18 U.S.C. § 2. The Superseding Information also includes a forfeiture allegation, pursuant to 18 U.S.C. § 982(a)(7)(C) and 28 U.S.C. § 2461(c).

The felony misbranding offense listed in Count I carries a maximum punishment of five years probation, a maximum fine of the greatest of $500,000, twice the gross amount of any pecuniary gain, or twice the gross amount of any pecuniary loss, and a $400 special assessment.

The misdemeanor counterfeit drug offense listed in Count II carries a maximum punishment of five years probation, a maximum fine of the greatest of $200,000, twice the gross amount of any pecuniary gain, or twice the gross amount of any pecuniary loss, and a $125 special assessment.

The advisory guideline range calculation contained within the pre-plea presentence report for these organizational defendants is calculated at 1 to 5 years probation, a guideline fine range of $4,994,694.60 to $9,989,389.20, and special assessments of $400 and $125, respectively, for the felony and misdemeanor

counts listed in the Superseding Information. Neither party has lodged any objection to the PSR as submitted.

RELEVANT FACTS

In 2001, Canada-based Kristjan Thorkelson founded CanadaDrugs.com Partnership and related corporate entities (hereinafter, "Canada Drugs") as an online pharmacy based in Winnipeg, Canada. PSR ¶ 36. Canada Drugs' business model was based on illegally importing unapproved and misbranded prescription pharmaceutical drugs into the United States from abroad and selling the drugs illegally to consumers throughout the United States in violation of 21 U.S.C. § 331(a). *Id*. The drugs were illegally imported into the United States through the systematic use of fraudulent customs declaration forms, which consistently undervalued the price of the drug products in order to avoid detection by United States regulatory and law enforcement authorities. *Id*. ¶¶ 33, 48-51, 56-57. The prescription drugs distributed in the United States by the Defendants were not approved by the FDA, and were misbranded as defined in the Food Drug and Cosmetic Act pursuant to 21 U.S.C. §§ 352(c), 352(o), and 352(f), as the products contained language on the labeling that was not in English, failed to contain adequate warnings and required statements, and lacked adequate directions for use. The United States has identified at least $78 million in gross proceeds received by

the Defendants as a result of their illegal prescription drug distribution scheme. *Id*. ¶ 47. Additionally, employees and executives of the Defendants were aware that they were selling prescription drugs in the United States that were not approved by the FDA. *Id*. ¶¶ 42, 48, 50, 52, 54, 55, 57.

In addition to being the Canada Drugs CEO, Thorkelson was also listed as the Director of Global Drug Supply, a subsidiary of Canada Drugs. PSR ¶ 30. Ronald Sigurdson was the Chief Financial Officer of Canada Drugs, and he assisted in the management of distribution operations along with Canada Drugs Clinical Manager Troy Nakamura, and Director of Clinical Sales for Canada Drugs, Darren Chalus. James Trueman served as a liaison between Canada Drugs and the drop shippers used by the corporate Defendants in the United States. *Id*. ¶¶ 30-33. Thomas Haughton was the President of two entities related to Canada Drugs, and he helped manage the operations of Canada Drugs' affiliate in the United Kingdom. *Id*.

After approximately eight years of operating this illegal scheme, in 2009, Canada Drugs expanded its market to include acquiring prescription drugs, including life-saving cancer medication, intended for sale in foreign countries, and illegally smuggling the drugs into the United States for distribution. *Id*. ¶ 37. As part of this expansion, Canada Drugs acquired other companies engaged in similar

illegal prescription drug importation and distribution activities, and used the brand names, drug inventories, and customer lists of those companies to further its illegal operation. *Id*. Those brand names included QP Medical, Quality Specialty Products, Bridgewater Medical, Clinical Care, and A+ Health Supplies. *Id*. ¶ ¶ 46. A majority of the prescription drugs, including cancer medication, were intended solely for foreign markets.

In July 2009, Canada Drugs created a new entity, organizational Defendant Rockley Ventures, Ltd., to operate its new clinical line of products. Rockley Ventures consisted of three companies acquired by Canada Drugs – Quality Specialty Products, Clinical Care, and Montana Healthcare Solutions (MHCS). *Id*. ¶ 38.

In 2009 and 2010, executives of the organizational Defendants, Thorkelson, Haughton, and Chalus, negotiated for the purchase of MHCS from Montana resident Paul Bottomley. The transaction was finalized in October 2010, when Bottomley sold MHCS to Canada Drugs and Rockley Ventures for $5 million. *Id*. ¶ 38. Bottomley was also to remain as an advisor for Canada Drugs following the sale, and Bottomley was paid $10,000 per month for his services. As part of the sale of MHCS, all non-FDA approved pharmaceutical drugs were shipped from Montana to Canada or to a shipping company in the United States under contract

with the Defendants. The Defendants also retained Bottomley's physician customer distribution list and continued to solicit and distribute to Bottomley's previous customers using his company's name and letterhead. After the purchase of MHCS, the Defendants continued to use MHCS' bank account at First Montana Bank to deposit funds from physicians for sales of unapproved and misbranded prescription drugs purchased in the United States from the Canada Drugs network of clinical sales. *Id*. ¶ 47. The funds from that account at First Montana Bank were then transferred by Bottomley to accounts of the corporate Defendants in Canada and Barbados. *Id*. (In 2013, Bottomley pleaded guilty in the District of Montana to the felony crime of misprision of a felony, in violation of 18 U.S.C. § 4, in connection with his conduct related to the Defendants in this case.)

Rockley Ventures was created with capital from Canada Drugs and was operated out of Barbados. United Kingdom-based organizational Defendant River East Supplies, Ltd., a subsidiary of Canada Drugs, primarily supplied the clinical arm with products for shipment to the United States. Haughton was the president of Rockley Ventures, and both he and Narinder Kaulder, Head of United Kingdom Operations, managed River East Supplies. *Id*. ¶ 31-32. The clinical arm of Canada Drugs used a model that involved drop shippers in the United States. Rockley Ventures or a subsidiary would place the order with a supplier for the unapproved

and/or misbranded drugs in gross. The products would then be shipped to a drop shipper in the United States for individual distribution to customers throughout the United States.

During the criminal investigation, it was discovered that the Defendants had distributed in the United States counterfeit cancer drug Avastin (American version) and counterfeit cancer drug Altuzan (Turkish version). *Id*. ¶¶ 40-56. Specifically, the counterfeit Altuzan was distributed in 2011 by River East Supplies. Authorities were only able to track a portion of the counterfeit packs of Altuzan because River East Supplies did not maintain adequate drug tracing and transaction documents. *Id*. ¶ 44. Substance analysis conducted by the FDA revealed that the Altuzan vials were counterfeit as they contained no active ingredient.

The counterfeit Avastin distributed by Canada Drugs-affiliated entities was discovered in December 2011, when the United Kingdom Medicines and Healthcare Products Regulatory Agency notified the FDA of a potential counterfeit batch of oncology drug Avastin that River East Supplies had purchased from a supplier in the European Union. *Id*. ¶ 42. Specifically, River East Supplies had acquired 167 packages of Avastin 400 mg and had transferred 41 of those packs to a drop shipper used by the Defendants in the United States. *Id*. That drop shipper confirmed that they had already sold and shipped 36 of the 41 vials of Avastin to

physicians in the United States. *Id*. Subsequent lab tests confirmed that the Avastin was counterfeit and contained none of the active ingredient bevacizumab that is found in legitimate versions of the oncology drug. *Id*. ¶ 50.

By at least early 2012, the Defendants were aware that the Canada Drugs affiliated companies had sold packages of suspect Avastin and Altuzan to medical clinics in the United States. *Id*. ¶¶ 40-41. Yet, at that time, the Defendants failed to notify any authorities regarding the suspect product. Further, the Defendants took steps to conceal the same. For example, in December 2011, one employee of the Defendants contacted a medical practice that had purchased a supply of the suspect Avastin and requested that the office return the product. *Id*. ¶ 40. The employee falsely stated that there was no problem with the product, and the medical practice was never told that the cancer medication was suspected of being counterfeit. *Id*. Additionally, in March 2012, Canada Drugs CEO Thorkelson sent an email message to all Canada Drugs employees falsely stating that Canada Drugs had "absolutely no connection to selling or offering Avastin." *Id*. ¶ 52. Thorkelson further falsely stated in that email message that Canada Drugs sold "only prescription maintenance medications to individuals." *Id*. By the time that email message had been sent, executives of the Defendants were aware that the statements in that message were false, and that the Defendants had already taken

efforts to recall the suspect Avastin from customers in the United States. *Id*. ¶¶ 40-56

In July 2013, FDA Office of Criminal Investigation agents learned that executives and employees of the Defendants systematically undervalued the declared value of each shipment of pharmaceutical drugs on customs forms in order to conceal the illegal importation of the unapproved and misbranded drugs into the United States. *Id*. ¶¶ 13, 48, 33, 56. Even after the drop-shippers used by the Defendants questioned the valuation of the products on the customs forms as well as the listing of the contents of the packages, an executive of the Defendants falsely informed the drop shipper that the Defendants were following all legal requirements for the importation of the drugs into the United States. *Id*. The executive of the Defendants suggested making changes to correct the customs declarations. However, despite that attempt to alleviate the concerns of the drop shipping company, the Defendants continued to use fraudulent customs declarations in furtherance of their smuggling scheme. *Id*.

SENTENCING RECOMMENDATION

The Government believes that the following disposition of the case against the organizational Defendants per the plea agreement entered into pursuant to Rule 11(c)(1)(C) of the Federal Rules of Criminal Procedure is supported by a fair

assessment of the advisory guideline calculation as well as the factors set forth in 18 U.S.C. § 3553(a) and relevant case law:

1) The Defendants will be sentenced to a period of probation of five years for Counts I and II to run concurrently;
2) The Defendants will forfeit $29 million of the proceeds of their illegal drug importation and distribution scheme;
3) The Defendants will pay a fine of $5 million to be imposed jointly and severally on the corporate Defendants;
4) The Defendants, their subsidiaries and all other related entities shall permanently cease all sales of unapproved, misbranded, adulterated, and counterfeit drugs in the United States within 90 days of the sentencing date;
5) The Defendants, their subsidiaries, and all other related entities shall surrender to the United States all domain names and any legal rights to the use of the domain names used in the importation, sale, or distribution of the violative products in this case;
6) The Defendants agree not to disclose any customer information of individuals residing in the United States to any other individual or business;

7) The Defendants agree to fully cooperate with the United States in this ongoing criminal investigation and future criminal investigations of the importation, sale, or distribution of violative products;

8) The Defendants will each pay a special assessment as listed in the PSR;

9) The Defendants agree that the plea agreement is contingent on the Court's acceptance of the guilty plea of individual co-defendant Thorkelson; and

10) The Defendants waive any right to appeal the judgment and sentence and the right to bring any other post-conviction attack;

If the Defendants plead guilty to the respective charges discussed above, the Government will move to dismiss the criminal charges against the following corporate and individual co-defendants, Global Drug Supply, Thorkelson Consulting, 4208081 Canada, Thomas Haughton, Ronald Sigurdson, Troy Nakamura, Darren Chalus, Narinder Kaulder, and Jim Trueman. The United States also recommends discretionary restitution in the amount of $30,250 to Eli Lilly and Company for costs incurred in participating in the criminal investigation of the Defendants.

The Court should impose the sentence on the defendants that the parties have agreed to pursuant to Rule 11(c)(1)(C) as it reflects the seriousness of the organizational defendants' crimes and provides just punishment for the offenses, under 18 U.S.C. § 3553(a).

The United States believes that the above-referenced sentence is an appropriate one reflecting the seriousness of the Defendants' offenses, the need for just punishment, and adequate deterrence to future criminal conduct. Although it is only one factor that the Court should rely upon in assessing the reasonableness of a sentence, the sentence agreed to by the parties is within the advisory guideline range for the offenses of conviction, as calculated in the PSR.

The United States FDA is a federal agency whose critically important mission is to protect and promote public health by assuring the safety, efficacy, and security of prescription drugs, among many other items. A significant goal of the FDA in protecting the nation's prescription drug supply is to reduce the likelihood of poor quality, unsafe, ineffective, and counterfeit products from entering the legitimate United States drug supply chain. In contrast, the goal of the Defendants' criminal scheme was to breach the integrity of the supply chain for financial gain, resulting in the health of United States consumers being endangered. As a direct result of the Defendants' illegal conduct, consumers and patients, including those needing life-saving chemotherapy, were at risk of receiving drugs that were not

approved by the FDA for use in the United States, were not in the proper supply chain, which had routes and storage that could not be verified, or were counterfeit.

The recommended sentence is reasonable as it importantly shuts down the large network of businesses operating this vast drug importation and distribution scheme under the Canada Drugs umbrella, disgorges the entities of substantial proceeds of their illegal scheme, mandates assistance by the Defendants in ongoing and future criminal investigations, and avoids the expenditure of additional significant time and resources by the United States in continuing to seek the extradition to the United States of individual co-defendants and continuing to litigate the receipt of evidence from abroad through pending mutual legal assistance treaty requests.

CONCLUSION

The organizational Defendants in this case operated a large-scale prescription drug scheme that placed profits ahead of the health and safety of consumers in the United States. Considering the foregoing, and all of the

sentencing factors, the United States respectfully submits that a sentence as requested herein is warranted and should be imposed by the Court.

DATED this 4th day of April, 2018.

KURT G. ALME
United States Attorney

/s/ Chad C. Spraker
Assistant United States Attorney
Attorney for Plaintiff

/s/ Paul Joseph
Special Assistant United States Attorney
Attorney for Plaintiff

CERTIFICATE OF COMPLIANCE

Pursuant to D. Mont. LR 7.1(d)(2) and CR 12.1(e), the attached United Sentencing Memorandum is proportionately spaced, has a typeface of 14 points or more, and has a body containing 3125 words.

/s/ Chad C. Spraker
Assistant United States Attorney
Attorney for Plaintiff

/s/ Paul Joseph
Special Assistant United States Attorney
Attorney for Plaintiff